

20201, call ahead to arrange for inspection at 202-690-7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH-1211, Geneve 20, Switzerland, telephone +41-22-749-01-11, <http://www.iso.org>.

(1) ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories (Second Edition), May 15, 2005, IBR approved for § 170.420 and § 170.423.

(2) ISO/IEC GUIDE 65 General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 170.420 and § 170.423.

(3) [Reserved]

Subpart E—Permanent Certification Program for HIT

SOURCE: 76 FR 1325, Dec. 7, 2011, unless otherwise noted.

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, subpart E was amended by removing the phrases “permanent certification program for HIT” and “permanent certification program” and add in their place “ONC HIT Certification Program” wherever they may occur, effective Oct. 4, 2012.

§ 170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the permanent certification program for health information technology (HIT) administered by the National Coordinator for Health Information Technology.

§ 170.501 Applicability.

This subpart establishes the processes that applicants for ONC-ACB status must follow to be granted ONC-ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC-ACB status; the requirements that ONC-ACBs must follow to maintain ONC-ACB status; and the requirements of ONC-ACBs for certifying Complete EHRs, EHR Module(s), and other types of HIT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also

establishes the processes accreditation organizations must follow to request approval from the National Coordinator and that the National Coordinator in turn will follow to approve an accreditation organization under the permanent certification program as well as certain ongoing responsibilities for an ONC-AA.

§ 170.502 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC-ACB by submitting an application for ONC-ACB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT resides or is being or has been implemented.

Development site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT was developed.

Gap certification means the certification of a previously certified Complete EHR or EHR Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).

ONC-Approved Accreditor or ONC-AA means an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

ONC-Authorized Certification Body or ONC-ACB means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the certification of Complete EHRs, EHR Module(s), and/or other types of HIT under the permanent certification program.

Providing or provide an updated certification means the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC-ACB

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has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module(s).

Remote certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC-ACB to be physically present at the development or deployment site to conduct certification.

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, §170.502 was amended by revising the definition of “providing or provide an updated certification”, effective Oct. 4, 2012. For the convenience of the user, the revised text is set forth as follows:

§ 170.502 Definitions.

* * * * *

Providing or provide an updated certification means the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by §170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

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§ 170.503 Requests for ONC-AA status and ONC-AA ongoing responsibilities.

(a) The National Coordinator may approve only one ONC-AA at a time.

(b) *Submission.* The National Coordinator will publish a notice in the FEDERAL REGISTER to announce the 30-day period during which requests for ONC-AA status may be submitted. In order to be considered for ONC-AA status, an accreditation organization must submit a timely request in writing to the National Coordinator along with the following information to demonstrate its ability to serve as an ONC-AA:

(1) A detailed description of the accreditation organization’s conformance to ISO/IEC17011:2004 (incorporated by reference in §170.599) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (incorporated by reference in §170.599);

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(2) A detailed description of the accreditation organization’s accreditation, requirements as well as how those requirements would complement the Principles of Proper Conduct for ONC-ACBs and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Detailed information on the accreditation organization’s procedures that would be used to monitor ONC-ACBs;

(4) Detailed information, including education and experience, about the key personnel who review organizations for accreditation; and

(5) Procedures for responding to, and investigating, complaints against ONC-ACBs.

(c) Preliminary selection.

(1) The National Coordinator is permitted up to 60 days from the end of the submission period to review all timely submissions that were received and determine which accreditation organization is best qualified to serve as the ONC-AA.

(2) The National Coordinator’s determination will be based on the information provided, the completeness of an accreditation organization’s description of the elements listed in paragraph (b) of this section, and each accreditation organization’s overall accreditation experience.

(3) The accreditation organization that is determined to be the best qualified will be notified that it has been selected as the ONC-AA on a preliminary basis, subject to the resolution of the reconsideration process in §170.504. All other accreditation organizations will be notified that their requests for ONC-AA status have been denied. The accreditation organization that is selected on a preliminary basis shall not represent itself as the ONC-AA or perform accreditation(s) under the permanent certification program unless and until it receives written notice from the National Coordinator that it has been approved as the ONC-AA on a final basis pursuant to paragraph (d) of this section.

(4) Any accreditation organization that submits a timely request for ONC-AA status and is denied may request